STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE
729 CHURCH STREET
NASHVILLE, TENNESSEE 37247-6501

[***Date to come]***

Renard L. Murray
Associate Regional Administrator
Division of Medicaid
Centers for Medicare and Medicaid Services (CMS)
Atlanta Federal Center
61 Forsyth Street, S.W., Suite 4T20
Atlanta, GA 30303-8909

Dear Mr. Murray:

Action Transmittal 2005-2 is an amendment to the Tennessee Title XIX Medicaid State Plan, which is being forwarded to your office for review and approval. This plan amendment is being submitted to discontinue Tennessee Medicaid/TennCare coverage of adult dental. A copy of the public notice conducted in accordance with 42 CFR 447.205 is attached. ***[This document will be attached when the SPA is submitted to CMS.]*** We would appreciate the opportunity to work with you to coordinate the final effective date with the date of approval of our waiver amendment.

Should you have any questions or need additional information, please contact Susie Baird at (615) 741-0213.

Sincerely,

J. D. Hickey
Deputy Commissioner

JDH/D1025013

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 2005-2

2. STATE TENNESSEE

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN X AMENDMENT TO BE CONSIDERED AS NEW PLAN ☐ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
42 CFR 440 and 441

7. FEDERAL BUDGET IMPACT:
a. FFY 2004/2005 $
b. FFY 2005/2006 $

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 3.1-A, page 4
Attachment 3.1-B, page 4
.

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:

Attachment 3.1-A, page 4; Attachment 3.1.A.1, Item 10;
Attachment 3.1-B, page 4; Attachment 3.1.B.1, Item 10.

10. SUBJECT OF AMENDMENT: Amount Duration and Scope of Medical and Remedial Care and Services Provided to the Categorically and Medically Needy; Limitation on Amount, Duration and Scope of Medical Care and Services Provided – Adult Dental.

11. GOVERNOR'S REVIEW *(Check One)*:
X GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME: J. D. Hickey

14. TITLE: Deputy Commissioner

15. DATE SUBMITTED:

16. RETURN TO:
Tennessee Department of Finance and Administration
Bureau of TennCare
729 Church Street
Nashville, TN 37247-6501

Attention: George Woods

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

18. DATE APPROVED:

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:

22. TITLE:

23. REMARKS:

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

9. Clinic services.

/X / Provided: / / No limitations /X / With limitations*
/ / Not provided.

10. Dental services.

/ / Provided: / / No limitations / / With limitations*
/X/ Not provided.

11. Physical therapy and related services.

a. Physical therapy.

/ / Provided: / / No limitations / / With limitations*
/X/ Not provided.

b. Occupational therapy.

/ / Provided: / / No limitations / / With limitations*
/X/ Not provided.

c. Services for individuals with speech, hearing, and language disorders (provided by or under the supervision of a speech pathologist or audiologist).

/ / Provided: / / No limitations / / With limitations*
/X/ Not provided.

***Description provided on attachment.**

D1074349

State/Territory: Tennessee

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED
MEDICALLY NEEDY GROUP(S): Children Under 21; Pregnant Women.

8. Private duty nursing services.
/ / Provided / / No limitation / / With limitations*

9. Clinic services.
/X / Provided / / No limitation / X/ With limitations*

10. Dental services.
/ / Provided / / No limitation / / With limitations*

11. Physical therapy and related services.
a. Physical therapy.
/ / Provided / / No limitation / / With limitations*
b. Occupational therapy.
/ / Provided / / No limitation / / With limitations*
c. Services for individuals with speech, hearing, and language disorders provided by or under supervision of a speech pathologist or audiologist.
/ / Provided / / No limitation / / With limitations*

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.
a. Prescribed drugs.
/ X/ Provided / / No limitation /X / With limitations*
b. Dentures.
/ / Provided / / No limitation / / With limitations*

***Description provided on attachment.**

D1015013

STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE
729 CHURCH STREET
NASHVILLE, TENNESSEE 37247-6501

[Date to come]

Renard L. Murray
Associate Regional Administrator
Division of Medicaid
Centers for Medicare and Medicaid Services (CMS)
Atlanta Federal Center
61 Forsyth Street, S.W., Suite 4T20
Atlanta, GA 30303-8909

Dear Mr. Murray:

Action Transmittal 2005-3 is an amendment to the Tennessee Title XIX Medicaid State Plan, which is being forwarded to your office for review and approval. This plan amendment is being submitted to point out that methadone clinic services are not provided. A copy of the public notice conducted in accordance with 42 CFR 447.205 is attached. ***[This document will be attached when the SPA is submitted to CMS.]*** We would appreciate the opportunity to work with you to coordinate the final effective date with the date of approval of our waiver amendment.

Should you have any questions or need additional information, please contact Susie Baird at (615) 741-0213.

Sincerely,

J. D. Hickey
Deputy Commissioner

JDH/D1035013

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 2005-3

2. STATE: TENNESSEE

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN X AMENDMENT TO BE CONSIDERED AS NEW PLAN ☐ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
42 CFR 440 and 441

7. FEDERAL BUDGET IMPACT:
a. FFY 2004/2005 $
b. FFY 2005/2006 $

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 3.1-A, page 4; Attachment 3.1-A.1, Item 9;
Attachment 3.1-B, page 4; Attachment 3.1.B.1, Item 9.

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Attachment 3.1-A, page 4; Attachment 3.1.A.1, Item 9;
Attachment 3.1-B, page 4; Attachment 3.1.B.1, Item 9.

10. SUBJECT OF AMENDMENT:
Amount, Duration and Scope of Medical Remedial Care and Services Provided to Categorically and Medically Needy; Limitation on Amount, Duration and Scope of Medical Care and Services Provided – Clinic Services.

11. GOVERNOR'S REVIEW *(Check One)*:
X GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME: J. D. Hickey

14. TITLE: Deputy Commissioner

15. DATE SUBMITTED:

16. RETURN TO:
Tennessee Department of Finance and Administration
Bureau of TennCare
729 Church Street
Nashville, Tennessee 37247-6501

Attention: George Woods

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

18. DATE APPROVED:

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:

22. TITLE:

23. REMARKS:

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

9. Clinic services.

/X / Provided: / / No limitations /X / With limitations*
/ / Not provided.

10. Dental services.

/ / Provided: / / No limitations / / With limitations*
/X/ Not provided.

11. Physical therapy and related services.

a. Physical therapy.

/ / Provided: / / No limitations / / With limitations*
/X/ Not provided.

b. Occupational therapy.

/ / Provided: / / No limitations / / With limitations*
/X/ Not provided.

c. Services for individuals with speech, hearing, and language disorders (provided by or under the supervision of a speech pathologist or audiologist).

/ / Provided: / / No limitations / / With limitations*
/X/ Not provided.

***Description provided on attachment.**

D1045013

State/Territory: Tennessee

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED
MEDICALLY NEEDY GROUP(S): Children Under 21; Pregnant Women.

8. Private duty nursing services.
/ / Provided / / No limitation / / With limitations*

9. Clinic services.
/X / Provided / / No limitation / X/ With limitations*

10. Dental services.
/ / Provided / / No limitation / / With limitations*

11. Physical therapy and related services.
a. Physical therapy.
/ / Provided / / No limitation / / With limitations*
b. Occupational therapy.
/ / Provided / / No limitation / / With limitations*
c. Services for individuals with speech, hearing, and language disorders provided by or under supervision of a speech pathologist or audiologist.
/ / Provided / / No limitation / / With limitations*

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.
a. Prescribed drugs.
/ X/ Provided / / No limitation /X / With limitations*
b. Dentures.
/ / Provided / / No limitation / / With limitations*

***Description provided on attachment.**

D1055013

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT, DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

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9. Clinic Services

The following types of clinic services are covered with limitations described for each.

a. Community Mental Health Centers – Services limited to those authorized to be provided.

b. Community Clinics

(1) Community Health Clinics, Community Health Agencies, Community Services Clinics.

Services limited to those authorized to be provided by each of the above type clinics.

(2) Ambulatory Surgical Centers – Services limited to those procedures designated by the state agency that can be performed outside the inpatient facility setting.

(3) Community Mental Retardation Clinics – Services provided by qualified community Mental Retardation Clinics shall be limited to medically necessary preventive, diagnostic, therapeutic, rehabilitative, or palliative services.

(4) Methadone clinic services are not covered.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT, DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

---

9. Clinic Services

The following types of clinic services are covered with limitations described for each.

a. Community Mental Health Centers – Services limited to those authorized to be provided.

b. Community Clinics

(1) Community Health Clinics, Community Health Agencies, Community Services Clinics.

Services limited to those authorized to be provided by each of the above type clinics.

(2) Ambulatory Surgical Centers – Services limited to those procedures designated by the state agency that can be performed outside the inpatient facility setting.

(3) Community Mental Retardation Clinics – Services provided by qualified community Mental Retardation Clinics shall be limited to medically necessary preventive, diagnostic, therapeutic, rehabilitative, or palliative services.

(4) Methadone clinic services are not covered.

STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE
729 CHURCH STREET
NASHVILLE, TENNESSEE 37247-6501

[Date to come]

Renard L. Murray
Associate Regional Administrator
Division of Medicaid
Centers for Medicare and Medicaid Services (CMS)
Atlanta Federal Center
61 Forsyth Street, S.W., Suite 4T20
Atlanta, GA 30303-8909

Dear Mr. Murray:

Action Transmittal 2005-4 is an amendment to the Tennessee Title XIX Medicaid State Plan, which is being forwarded to your office for review and approval. This plan amendment is being submitted to discontinue Tennessee Medicaid/TennCare coverage of payment made to reserve a bed during a recipient's temporary absence from a nursing facility. A copy of the public notice conducted in accordance with 42 CFR 447.205 is attached. ***[This document will be attached when the SPA is submitted to CMS.]*** We would appreciate the opportunity to work with you to coordinate the final effective date with the date of approval of our waiver amendment.

Should you have any questions or need additional information, please contact Susie Baird at (615) 741-0213.

Sincerely,

J. D. Hickey
Deputy Commissioner

JDH/D1075013

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: HEALTH CARE FINANCING ADMINISTRATION	1. TRANSMITTAL NUMBER: 2005-4	2. STATE TENNESSEE
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE	

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN X AMENDMENT TO BE CONSIDERED AS NEW PLAN ☐ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR 447.40	7. FEDERAL BUDGET IMPACT: a. FFY 2004/2005 $ b. FFY 2005/2006 $
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 4.19 C.	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: Attachment 4.19 C.

10. SUBJECT OF AMENDMENT: Methods of Reimbursing for Reserved Beds in Nursing Facilities and Intermediate Care Facilities for the Mentally Retarded.

11. GOVERNOR'S REVIEW *(Check One)*:

X GOVERNOR'S OFFICE REPORTED NO COMMENT

☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED

☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:	16. RETURN TO: Tennessee Department of Finance and Administration Bureau of TennCare 729 Church Street Nashville, Tennessee 37247-6501 Attention: George Woods
13. TYPED NAME: J. D. Hickey	
14. TITLE: Deputy Commissioner	
15. DATE SUBMITTED:	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:	18. DATE APPROVED:
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL:	20. SIGNATURE OF REGIONAL OFFICIAL:
21. TYPED NAME:	22. TITLE:

23. REMARKS:

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE TENNESSEE

METHODS OF REIMBURSING FOR RESERVED BEDS IN NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED

a. Medicaid does not reimburse for reserving a nursing facility bed. Nursing facility costs for reserving beds are not medical costs.

b. Reimbursement for reserved beds in an Intermediate Care Facility for the Mentally Retarded, (ICF/MR) is as follows:

(1) For days not to exceed 15 days per occasion while the recipient is hospitalized and the following conditions are met:

(a) The resident intends to return to the ICF/MR.

(b) The hospital provides a discharge plan for the resident.

(c) At least 85% of all other beds in the ICF/MR certified at the recipient's designated level of care (i.e. intensive training, high personal care or medical), when computed separately, are occupied at the time of the hospital admission.

(d) Each period of hospitalization must be physician ordered and so documented in the patient's medical record in the ICF/MR.

(2) For days not to exceed 36 days per fiscal year while the recipient, pursuant to a physician's order, is absent from the facility on a therapeutic home visit or other therapeutic absence.

D1085013

STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE
729 CHURCH STREET
NASHVILLE, TENNESSEE 37247-6501

[Date to come]

Renard L. Murray
Associate Regional Administrator
Division of Medicaid
Centers for Medicare and Medicaid Services (CMS)
Atlanta Federal Center
61 Forsyth Street, S.W., Suite 4T20
Atlanta, GA 30303-8909

Dear Mr. Murray:

Action Transmittal 2005-5 is an amendment to the Tennessee Title XIX Medicaid State Plan, which is being forwarded to your office for review and approval. This Plan Amendment points out that the only Optional Medically Needy Groups covered under the State plan are pregnant women and children. A copy of the public notice conducted in accordance with 42 CFR 447.205 is attached. ***[This document will be attached when the SPA is submitted to CMS.]*** We would appreciate the opportunity to work with you to coordinate the final effective date with the date of approval of our waiver amendment.

Should you have any questions or need additional information, please contact Susie Baird at (615) 741-0213.

Sincerely,

J. D. Hickey
Deputy Commissioner

JDH/D1095013

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL **FOR: HEALTH CARE FINANCING ADMINISTRATION**	1. TRANSMITTAL NUMBER: 2005-5	2. STATE TENNESSEE
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE	

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN X AMENDMENT TO BE CONSIDERED AS NEW PLAN ☐ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR 435	7. FEDERAL BUDGET IMPACT: a. FFY 2004/2005 $ b. FFY 2005/2006 $
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 2.2-A, pages 24 and 26.	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: Attachment 2.2-A, pages 24 and 26.

10. SUBJECT OF AMENDMENT:
Groups Covered and Agencies Responsible for Eligibility Determination - Optional Coverage of the Medically Needy.

11. GOVERNOR'S REVIEW *(Check One)*:
X GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:	16. RETURN TO: Tennessee Department of Finance and Administration Bureau of TennCare 729 Church Street Nashville, Tennessee 37247-6501 Attention: George Woods
13. TYPED NAME: J. D. Hickey	
14. TITLE: Deputy Commissioner	
15. DATE SUBMITTED:	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:	18. DATE APPROVED:
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL:	20. SIGNATURE OF REGIONAL OFFICIAL:
21. TYPED NAME:	22. TITLE:

23. REMARKS:

State: Tennessee

Agency*	Citations(s)	Groups Covered
	C.	Optional Coverage of the Medically Needy
42 CFR 435.301		This plan includes the medically needy.
		/_/ No.
		/X/ Yes. This plan covers the following groups:
		• Pregnant women and children.
	1.	Pregnant women who, except for income and/or resources, would be eligible as categorically needy under title XIX of the Act.
1902(e) of the Act	2.	Women who, while pregnant, were eligible for and have applied for Medicaid and receive Medicaid as medically needy under the approved State plan on the date the pregnancy ends. These women continue to be eligible, as though they were pregnant, for all pregnancy-related and postpartum services under the plan for a 60-day period, beginning with the date the pregnancy ends, and any remaining days in the month in which the 60th day falls.
1902(a)(10)(C) (ii)(I) of the Act	3.	Individuals under age 18 who, but for income and/or resources, would be eligible under section 1902(a)(10)(A)(i)of the Act.

*Agency that determines eligibility for coverage.

D1014261

State: Tennessee

Agency*	Citations(s)		Groups Covered
	C.		Optional Coverage of the Medically Needy (Continued)
42 CFR 435.310	/_/	6.	Caretaker relatives.
42 CFR 435.320 and 435.330	/_/	7.	Aged individuals.
42 CFR 435.322 and 435.330	/_/	8.	Blind individuals.
42 CFR 435.324 And 435.330	/_/	9.	Disabled individuals.
42 CFR 435.326	/_/	10.	Individuals who would be ineligible if they were not enrolled in an HMO. Categorically needy individuals are covered under 42 CFR 435.212 and the same rules apply to medically needy individuals.
435.340		11.	Blind and disabled individuals who: a. Meet all current requirements for Medicaid eligibility except the blindness or disability criteria; b. Were eligible as medically needy in December 1973 as blind or disabled; and c. For each consecutive month after December 1973 continue to meet the December 1973 eligibility criteria.

*Agency that determines eligibility for coverage.

D1105013

STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE
729 CHURCH STREET
NASHVILLE, TENNESSEE 37247-6501

[Date to Come]

Renard L. Murray
Associate Regional Administrator
Division of Medicaid
Centers for Medicare and Medicaid Services (CMS)
Atlanta Federal Center
61 Forsyth Street, S.W., Suite 4T20
Atlanta, GA 30303-8909

Dear Mr. Murray:

Action Transmittal 2005-6 is an amendment to the Tennessee Title XIX Medicaid State Plan, which is being forwarded to your office for review and approval. This plan amendment is being submitted to eliminate coverage for over the counter drugs, limit prescriptions to four (4) for Medicaid adults, and institute co-pays for Medicaid adults. A copy of the public notice conducted in accordance with 42 CFR 447.205 is attached**. [*This document will be attached when the SPA is submitted to CMS].*** We would appreciate the opportunity to work with you to coordinate the final effective date with the date of approval of our waiver amendment.

Should you have any questions or need additional information, please contact Susie Baird at (615) 741-0213.

Sincerely,

J. D. Hickey
Deputy Commissioner

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 2005-6

2. STATE: TENNESSEE

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN X AMENDMENT TO BE CONSIDERED AS NEW PLAN ☐ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
42 CFR 440 and 441

7. FEDERAL BUDGET IMPACT:
a. FFY 2004/2005 $
b. FFY 2005/2006 $

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 3.1.A.1, Item 12.
Attachment 3.1.B.1, Item 12

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Attachment 3.1.A.1, Item 12.
Attachment 3.1.B.1, Item 12.

10. SUBJECT OF AMENDMENT:
Limitation on Amount, Duration and Scope of Medical Care and Services Provided – Prescribed Drugs.

11. GOVERNOR'S REVIEW *(Check One)*:
X GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME: J. D. Hickey

14. TITLE: Deputy Commissioner

15. DATE SUBMITTED:

16. RETURN TO:
Tennessee Department of Finance and Administration
Bureau of TennCare
729 Church Street
Nashville, Tennessee 37247-6501

Attention: George Woods

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

18. DATE APPROVED:

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:

22. TITLE:

23. REMARKS:

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT, DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

12.a. Prescribed drugs

(1) Prescription outpatient drugs of any manufacturer which has entered into and complies with an agreement under Section 1927(a) of the Social Security Act will be a covered benefit for all Medicaid eligible TennCare members when prescribed by an authorized licensed prescriber, unless coverage is excluded or otherwise restricted by TennCare in accordance with the following:

(a) As provided by Section 1927(d) of the Social Security Act, hereinafter referred to as the Act, the following drugs or classes of drugs or their medical uses are allowed to be excluded from coverage or otherwise restricted: agents when used for anorexia or weight control, agents when used to promote fertility, agents when used for cosmetic purposes or hair growth, agents when used for the symptomatic relief of coughs and colds, agents when used to promote smoking cessation, nonprescription or "over-the-counter" ("OTC") drugs, even when prescribed by a physician, covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests and monitoring services be purchased exclusively from the manufacturer or its designee, and drugs described in Section 107(c)(3) of the Drug Amendments of 1962 and identical, similar, or related drugs (DESI, IRS and LTE) as described in Section 1903(i)(5) of the Social Security Act. TennCare will exclude from coverage all of the allowable exclusions described above, with the exception of OTC drugs prescribed as medically necessary for individuals under the age of 21, and pre-natal vitamins prescribed for pregnant women.

(b) Services or treatment received from Methadone treatment clinics will be excluded from coverage.

(c) Coverage of prescription drugs for adult beneficiaries 21 years of age or older, who are not receiving services in a nursing facility (or other facility for institutional care) or enrolled in a Home and Community Based Services (HCBS) waiver, will be limited to four prescriptions per

month. This coverage limitation shall not apply to medications or supplies included on the list attached to this State Plan as Attachment I, or to such other medications as may subsequently be designated by the State through appropriate policy issuances, and of which pharmacies, providers and beneficiaries shall be made aware through appropriate notice.

(2) No payment will be made for an innovator multiple source drug (brand name drug) if, under applicable State law, a less expensive multiple source drug could have been dispensed, but only to the extent that such amount exceeds the upper payment limit for such multiple source drug. In the event a prescriber indicates on the face of the prescription ("dispense as written") that he/she is requiring a specific brand name drug be dispensed for a specific TennCare member or if a TennCare member appeals coverage of a generic drug and the appeals process results in approval of a specific brand name drug, then the reimbursement methodology for that prescription will the same as that for innovator single source drugs covered under the TennCare pharmacy program.

(3) A prior approval system for drugs requiring prior authorization will comply with Section 1927 of the Act and be administered by the pharmacy benefits manager (PBM) or pharmacy benefits administrator (PBA) under contract to TennCare to provide those services. The prior authorization process provides for a turn-around response by either telephone or other telecommunications device within twenty-four hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a seventy-two hour supply of medication.

(4) Participating pharmaceutical manufacturers will be furnished drug rebate utilization data and allowed to audit this data as set forth and according to the Centers for Medicare and Medicaid Services (CMS) guidelines pursuant to the Act.

(5) As provided by the Act, a new drug manufactured by a company which has entered into a rebate agreement may be covered subject to prior approval, unless the drug is subject to the allowable exclusion categories provided by the Act.

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(6) As specified in section 1927(b)(3)(D) of the Act, notwithstanding any other provision of law, information disclosed by manufacturers shall not be disclosed by the State in a form which discloses the identity of a specific manufacturer or prices charged for drugs by such manufacturers, except as the Secretary determines to be necessary and/or to permit the Comptroller General to review the information provided.

(7) Separate agreements between the State and the manufacturers require CMS authorization. The State has CMS authorization for the collection of supplemental rebates that are negotiated with pharmaceutical manufacturers pursuant to the TennCare preferred drug list (PDL) as required by the Act. TennCare will report supplemental rebates from separate agreements to CMS.

(8) The state is in compliance with Section 1927 of the Social Security Act, except insofar as the State may have obtained a waiver of § 1902(a)(54) of the Social Security Act under § 1115 to authorize noncompliance with certain provisions of § 1927 for specific purposes related to carrying out a federally approved demonstration project. Except as otherwise specifically provided in this State Plan, the state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and applicable restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.

A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on August 13, 2003 and entitled, "State of Tennessee Supplemental Rebate Agreement," has been authorized by CMS.

Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

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All drugs covered by the program, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

(9) Adult beneficiaries 21 years of age or older shall be liable for nominal cost sharing in the expense of outpatient pharmacy services afforded to them under the State Plan, and shall be obligated to make nominal co-payments when receiving covered prescription drugs from a pharmacy or other provider, with the exception of generic drugs included on the State's preferred drug list and drugs in categories that have not been reviewed for the inclusion in the preferred drug list. Pharmacies or providers shall collect all applicable TennCare-required copays from TennCare members. Failure to make an applicable co-payment will not be a basis for delay or denial of any of the services described in Section 1916(a)(2) of the Social Security Act or implementing regulations at 42 C.F.R. 447.53(b). Services cannot be denied to any eligible recipient because of the individual's inability to pay the co-payment. This requirement does not apply to an individual who is able to pay. An individual's inability to pay does not eliminate his or her liability for the co-payment charges. A recipient is deemed unable to pay the co-payment if the recipient states to the pharmacist that he or she cannot pay. The amount of such co-payment will be $1.00 for each prescription filled of a branded drug on the State's preferred drug list, and $3.00 for non-preferred medications. Certain enrollees will be exempt from copay obligations, in accordance with 42 CFR 447.53(b).

(10) In accordance with the provisions of the Act, TennCare began the development and implementation of a preferred drug list (PDL) on July 1, 2003. TennCare will move to a single, statewide preferred drug list (PDL) for the entire pharmacy program. Furthermore, TennCare will employ a single pharmacy benefits manager (PBM) to process all TennCare pharmacy claims and respond to all prior approval requests.

Pursuant to 42 U.S.C. Section 1396r-8 the state is establishing a preferred drug list with prior authorization for drugs not included on the preferred drug list. Prior authorization will be provided with a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in emergency situations.

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Prior authorization will be established for certain drug classes, particular drugs or medically accepted indication for uses and doses.

The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.

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(11) Except as otherwise specifically provided in this State Plan, when a provider with prescribing authority prescribes a covered medication for a TennCare member, and the prescription is presented at a pharmacy that participates in the TennCare program, the member is entitled to either:

(a) The drug as prescribed, if the drug is covered by TennCare and does not require prior authorization; or

(b) The drug as prescribed, if the prescribing provider has obtained prior authorization; or

(c) An alternative medication, if the pharmacist consults the prescribing provider when the member presents the prescription to be filled, and the provider prescribes the substituted drug; or

(d) An emergency supply of the prescribed drug, if the pharmacist is unable, when the member presents the prescription to be filled, to obtain authorization from either TennCare or the designated TennCare point-of-sale (POS) pharmacy claims processor to fill the prescription as written or the prescribing provider's authorization to substitute an alternative medication. If the member does not receive the medication of the type and amount prescribed, the pharmacist shall immediately provide written notice of the right to appeal, including the right to request continuation of services pending appeal, as required by the *Grier* Revised Consent Decree. The member's entitlement to receive an emergency supply of the prescribed drug is subject to the provisions as set out below.

(12) The member is entitled to an emergency supply of the prescribed drug provided that:

(a) The manufacturer has a rebate agreement and the medication is not classified by the FDA or regarded by CMS to be less than effective (DESI, LTE or IRS drug); or

(b) The medication is not a drug in a non-covered TennCare therapeutic category or class of drugs or products such as: agents used for anorexia, weight loss or weight gain, agents used to promote fertility, agents not listed on the TennCare preferred drug list used for the symptomatic relief of cough and colds, agents used for cosmetic purposes or hair growth, agents used to promote smoking cessation, agents not listed on the TennCare drug preferred drug list which are prescription vitamins and mineral products, agents not listed on the TennCare preferred drug list which are nonprescription (over-the-counter) products and drugs. TennCare will exclude from coverage all of the allowable exclusions described above; or

(c) Use of the medication has not been determined to be medically contraindicated because of the member's medical condition or possible adverse drug interaction; or

(d) The prescriber did not prescribe a total quantity less than an emergency supply, in which case the pharmacist must provide a supply up to the amount prescribed.

(13) There are some cases in which it is not feasible for the pharmacist to dispense an emergency supply because the drug is packaged by the manufacturer to be sold as the original unit or because the usual and customary pharmacy practice would be to dispense the drug in the original packaging (inhalers, eye drops, topicals, etc.). When coverage of an emergency supply of a prescription would otherwise be required and when, as described above, it is not feasible for the pharmacist to dispense an emergency supply, it shall be the responsibility of TennCare to provide coverage for either the emergency supply or the usual dispensing amount, whichever is greater.

(14) Pharmacies should bill prescriptions for TennCare members with other third party insurance to the appropriate third party payer (primary insurer) and bill any applicable copays for covered drugs to TennCare.

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(15) Covered drugs under the TennCare Pharmacy Program shall be limited to drugs that meet one or more of the following criteria and are not excluded by any of the following criteria:

(a) Those legend drugs covered under the Medicaid Drug Rebate Program as described in Section 1927 (k) of the Social Security Act and outlined in the TennCare Pharmacy Program Preferred drug list.

(b) Legend and non-legend drugs which are covered and prescribed by an authorized prescriber and which may not be dispensed over the counter without a prescription, except this limitation of coverage shall not apply in the case of a child under the age of 21 for whom an over-the-counter (OTC) drug has been prescribed as medically necessary by a licensed medical professional, or to coverage of pre-natal vitamins when prescribed for a pregnant woman.

(c) Those drugs which are not included in the list of excluded therapeutic categories or classes contained in Section 1927(d) of the Social Security Act and listed above in (12)(a)(1); and except to the extent such drugs may be expressly excepted from non-coverage or designated as covered under certain circumstances or for certain categories of beneficiaries under any provision of this State Plan.

(d) Those drugs not considered to be DESI, less-than-effective (LTE) or identical, related or similar (IRS) to DESI drugs.

(e) Drugs that are included on the State's formulary, except, where applicable, in a case where prior authorization is obtained for coverage of any such drug.

(f) Drugs that are not designated as excluded from coverage under Section 12.a.(1) or any other provision of this State Plan.

(g) Drugs that are not prescribed under circumstances, or for individuals, for which their use is designated as non-covered under Section 12.a.(1) or any other provision of this State Plan.

Attachment I
Pharmacy Shortlist

Medications that will continue to be available to patients **in an outpatient setting** (if provided by a participating health care provider) even after the physician office visit or outpatient facility visit limit has been reached **or** that will **not** count toward the 4 prescription limit when obtained through a participating retail pharmacy:

Specified drugs for the treatment of renal disease (iron preparations and dialysis medications)
TPN
Antineoplastic agents
Clotting factors
Antiviral agents specific to HIV treatment
Drugs specific to the treatment of Hep C
Drugs specific to the treatment of tuberculosis
Flu vaccine for high risk individuals
Prenatal vitamins

This list has been developed in consultation with state health associations, attempting to take into account the following factors:

(1) actual budget constraints;
(2) associated severity of illness;
(3) likelihood that the patient will require multiple drugs; and
(4) abuse potential and current utilization levels.

Equipment and Supplies that will not count toward any limit and that will continue to be covered **in an outpatient setting** even after other benefit limits have been hit:

Home infusion supplies
Diabetic supplies
Asthma supplies

Important Note:

The Shortlist is a living document. As new medications become available that fall into the same or similar categories to those already on the list, they will be considered for inclusion on the list. In addition, the list will be reviewed in the regularly in the context of budget constraints and operational compliance and could be expanded or reduced based on the results of such review. State health associations will be involved in decision-making.

	HIC3 Description		Examples of Paid Claims	HIC3 Coding	HICL coding
Clotting Factors	Antihemophilic Factors	Factor VIIa	Novoseven	**M0E**	011639
		Factor VII	Advate	**M0E**	011418
			Recombinate	**M0E**	011418
			Kogenate FS	**M0E**	011418
			Helixate FS	**M0E**	011418
			Refacto	**M0E**	011418
		Anti-inhibitor Coagulant Complex	Autoplex T	**M0E**	**002740**
			Fieba VH Immuno	**M0E**	**002740**
		Antihemophilic factor/von Willebrand factor	Humate-P	**M0E**	017395
		Antihemophilic factor	Alphanate	**M0E**	011417
			Hemofil-M	**M0E**	011417
	Factor IX Preparations	Factor IX	Benefix	**M0F**	012793
			Bebulin VH	**M0F**	002741
			Mononine	**M0F**	021313
			Alphanine SD	**M0F**	021313
Iron Preparations	Hematinic, other	Epoetin	Procrit	**N1B**	004553
			Epogen	**N1B**	004553
		Darbepoetin	Aranesp	**N1B**	048578
	Iron replacement	Iron Dextran	Infed	C3B	**000733**
			DexFerrum	C3B	**000733**
		Sodium Ferric Gluconate Complex	Ferrlecit	C3B	**019948**
		Iron Sucrose	Venofer	C3B	**021773**
Dialysis Medications	Electolyte Depleters		Calcium Acetate	**C1A**	004884
			Sevelamar (Renagel)	**C1A**	018832
			SPS (Kayexalate)	**C1A**	013209
	Vitamin B preps		FA/Vit B Complex with C (Nephrocap)	C6B	**001061**
Anti-Virals	Antivirals, HIV Specific, Protease Inhibitor	Protease Inhibitors	Invirase	**W5C**	024470
			Fortovase	**W5C**	016624
			Norvir	**W5C**	010412
			Crixivan	**W5C**	010683
			Viracept	**W5C**	030366
			Lexiva	**W5C**	025662
			Agenerase	**W5C**	021177
			Agenerase	**W5C**	019079
			Reyataz	**W5C**	025390
	Antivirals, HIV specific, Protease Inhibitor Combo	Protease Inhibitor Combos	Kaletra	**W5M**	021582
	Antivirals, HIV specific, nucleotide analog RTI	Nucleotide Analog Reverse Trans Inhibitor	Viread	**W5I**	022937

	Antivirals, HIV specific nucleoside analog RTI	Nucleoside Rev Transcript Inhibitor	Videx	**W5J**	011013, 006508, 006510, 006221
			Epivir	**W5J**	024417
			Zerit	**W5J**	009060
			Hivid	**W5J**	006408
			Retrovir	**W5J**	004185
			Ziagen	**W5J**	018857
			Emtriva	**W5J**	025426
	Antivirals HIV specific nucleoside analog RTI combo	Nucleoside analog Reverse Trans Inhibitor	Combivir	**W5L**	014014
			Trizivir	**W5L**	021800, 022982
			Epzicom	**W5L**	026524
	Antiviral HIV specific nucleoside/nucleotide combo	Nucleoside/nucleotide combo	Truvada	**W5O**	026515
	Antivirals HIV specific non-nucleoside RTI	Non-nucleoside reverse trans inhibitor	Viramune	**W5K**	011592
			Rescriptor	**W5K**	012954
			Sustiva	**W5K**	018748
	Antivirals HIV specific fuseon inhibitor	Fuseon inhibitors	Fuzeon	**W5N**	025044
	Antivirals assoc with HIV	General antivirals	Foscavir	**W5A**	013221
			Cytovene (PO + IV)	**W5A**	009644
			Valcyte	**W5A**	022033
			Vistide	**W5A**	011506
	Eye antivirals	Eye antivirals	Vitravene	Q6V	**018834**
			Vitrasert	Q6V	**009644**
Flu Vaccine	Influenza virus vaccines		Influenza tri/split	**W7C**	
Hepatitis C	Hepatitis C treatment agents		Peg-interferon alfa-2a (Pegasys)	**W5G**	024035
			Peg-interferon alfa-2b	**W5G**	021367
			Ribavirin (Rebetrol)	**W5G**	004184
			Interferon alfa-2b and ribivirin (Rebetron)	**W5G**	018438
			Interferon alfacon-1 (Infergen)	**W5G**	015707

			Interferon alfa-2a (Roferon-A)	Z2G	**004527**
			Interferon alfa-2b (Intron A)	Z2G	**004528**
Anti-tubercular Agents	Anti-mycobacterium		Isoniazid	**W2E**	004080
			Rifabutin	**W2E**	007626
			Pyrazinamide	**W2E**	004084
			Ethambutol	**W2E**	004085
			Ethionamide	**W2E**	004086
			Aminosalicylic acid	**W2E**	004081, 004082, 004083
	Antitubercular antibiotics		Rifamate	**W1G**	004039
			Rifater	**W1G**	006296
			Rifampin	**W1G**	**004040**
			Cycloserine	**W1G**	004038
			Capreomycin	**W1G**	004037
			Rifapentine	**W1G**	018831
	Aminoglycoside		Streptomycin	W1F	004027
Antineoplastics	Alkylating agents	Nitrogen mustards	Chlorambucil	**V1A**	003894
			Cyclophosphamide	**V1A**	003893
			Ifosfamide	**V1A**	004570, 003903
			Mechlorethamine	**V1A**	004570, 003892
			Melphalan	**V1A**	007845, 003895
		Nitrosureas	Carmustine	**V1A**	003901
			Lomustine	**V1A**	003900
		Alkyl Sulfonates	Busulfan	**V1A**	003899
		Ethylenimines/Methylmelamines	Altretamine	**V1A**	006041
			Thiotepa	**V1A**	003898
		Platinum Coordination Complex	Carboplatin	**V1A**	003905
			Cisplatin	**V1A**	003902
			Oxaliplatin	**V1A**	016687
		Substituted Ureas	Hydroxyurea	**V1A**	003897

		Imidazotetrazine Derivatives	Temozolomide	**V1A**	020355
	Steroid antineoplastics	Estrogen/Nitrogen Mustard	Estramustine phos sod	**V1E**	003924
		Androgens	Testolactone	**V1E**	003922
	Antibiotic anti-neoplastics	Antibiotic anti-neoplastics	Streptozocin	**V1D**	003920
			Bleomycin	**V1D**	003918
			Dactinomycin	**V1D**	003914
			Mitomycin	**V1D**	003917
		Antibiotics, anthracyclines	Daunorubicin HCL	**V1D**	003919
			Daunorubicin liposomal	**V1D**	010804
			Doxorubicin	**V1D**	003916
			Doxorubicin, liposomal	**V1D**	010222
			Epirubicin	**V1D**	006578
			Idarubicin	**V1D**	006024
	Antineoplastics, Misc	Triazenes	Dacarbazine	**V1F**	003927
		Taxoids	Paclitaxel	**V1F**	010166, 007625
			Docetaxel	**V1F**	010280
		Podophyllotoxin Derivatives	Etoposide	**V1F**	011549, 003930
			Teniposide	**V1F**	004811
		Aromatase Inhibitors	Anastrozole	**V1F**	010249
			Letrozole	**V1F**	012351
			Exemestane	**V1F**	020803
		Enzymes	Asparaginase	**V1F**	003929
			Pegaspargase	**V1F**	008904
		Anthracenedione	Mitoxantrone	**V1F**	003932
		Methylhydrazine Derivatives	Procarbazine	**V1F**	003928
		DNA Topoisomerase Inhibitors	Irinotecan	**V1F**	010778
			Topotecan	**V1F**	011381
		Biological Response Modifiers	Aldesleukin	Z2G	**006402**
			BGC, Intravesical	**V1F**	004219
			Denileukin Diftitox	**V1F**	019075
			Levamisole	Z2G	**005811**
		Retinoids, antineoplastics	Tretinoin (Vesanoid only)	**V1F**	002468
		Rexinoids	Bexarotene	**V1N**	**020832**
				Q5N	**020832**
			Alitretinoin	Q5N	**019074**
		Misc	Mitotane	**V1F**	003925
			Porfimer	**V1R**	011790

			Talc Powder, sterile	**V1S**	002321
			Abarelix	**V1V**	025850
			Arsenic trioxide	**V1F**	021734
	Antimetabolites	Folic Acid Antagonists	Methotrexate	**V1B**	003905, 003906, 024819
			Pemetrexed	**V1B**	025905
		Pyrimidine analogs	Capecitabine	**V1B**	018385
			Gemcitabine	**V1B**	010798
			Cytarabine	**V1B**	003910
			Cytarabine, liposomal	**V1B**	020270
			Fluorouracil	**V1B**	003907
			Floxuridine	**V1B**	003909
		Purine analogs and related agents	Cladribine	**V1B**	007840
			Fludarabine	**V1B**	006308
			Mercaptopurine	**V1B**	003908
			Pentostatin	**V1B**	006304
			Thioguanine	**V1B**	003911
		DNA demethylation agents	Azacitidine	**V1B**	026361
	Antimitotic agents	Vinca alkaloids	Vinblastine	**V1C**	003912
			Vincristine	**V1C**	003913
			Vinorelbine	**V1C**	009614
	Hormones	Antiandrogens	Bicalutamide	**V1J**	010143
			Flutamide	**V1J**	003933
			Nilutamide	**V1J**	007876
		Antiestrogen	Tamoxifen	**V1T**	003926
			Toremifene	**V1T**	011632
			Fulvestrant	**V1T**	023523
		Gonadotropin-releasing hormone analog	Leuprolide	**V1O**	021994, 021102
			Goserelin	**V1O**	021114
			Triptorelin	**V1O**	023164
	Radiopharmaceuticals	Radiopharmaceuticals	Strontium-89	**V1G**	008779
			Samarium SM 153	**V1G**	013440
	Cytoprotective agents	Chemotherapy rescue/antidote agent	Amifostine	**V1I**	010704, 013015
			Dexrazoxane	**V1I**	009997
			Mesna	**V1I**	003934
			Leucovorin	**V1I**	001063
	Monoclonal antibodies	Antineoplastics antibody/antibody drug complex	Rituximab	**V1K**	016848
			Ibritumomab	**V1K**	023335, 023334
			Trastuzumab	**V1K**	018801

			Gemtuzumab	**V1K**	021218
			Alemtuzumab	**V1K**	022112
			Tositumomab	**V1K**	025481
			Zevalin	**V1K**	024430, 024431
				V1U	025481
		Antineoplastic egf receptor blocker rcmb mc antibody	Cetuximab	**V1W**	025947
		Antineoplastic hum vegf inhibitor recomb mc antibody	Bevacizumab	**V1X**	025963
	Protein tyrosine kinase inhibitors	Antineoplastic systemic enzyme inhibitor	Imatinib	**V1Q**	022096
	Epidermal growth factor receptor inhibitors	Antineoplastic systemic enzyme inhibitor	Cefitinib	**V1Q**	025178
	Proteasome Inhibitors	Proteasome Inhibitors	Bortezomib	**V1Q**	025202
		HER1/EGFR tyrosine kinase inhibitors	Erlotinib	**V1Q**	26745
					V1Q
Glucose regulating and monitoring agents	Test strips	HICL=006373, GSN=19756, 6373			
	Lancets	HICL=004422, 025583			
	Alcohol pads	HICL=004266			
	Glucose control solution	HICL=023579, GSN=19415			
	Meters	HICL=002748, 023088, 007894, 024300, 024299. gsn=6372			
	Syringes	HICL=004327, 023038, 023041, 023039, 023037, 023042, 023043, 024313, 024314, 024100, 023040, 024315, 025117, 025118			
Prenatal vitamins	Prenatal Vitamin preparations		Prenate, Zenate, etc	C6F	
Asthma Spacers				Y7A	**009021**

Large Volume Parenterals					
Coded by large volume fluid for quantities > 500ml, any additive will be covered					
Sodium Chloride	HICL 008254, 008643, GSN 1210, 1209				
Dextrose	HIC3 of C5K, C5L, C5M, HICL 000915, 000929				
Lactated Ringers	HIC3 of C1W				
Sterile Water	GSN 1166				
TPN					
Coded by Amino Acid, all additives will be covered					
Amino Acids	HIC3 of C5B				
Heplock					
Heplock of 10u/ml or 100u/ml	GSN 6551, 6552, 6531, 6532, 6541, 6542, 18063				
Saline Flush					
Coded up to 30cc vials	GSN 1218, 1221, HICL 003794				

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12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

12.a. Prescribed drugs

(1) Prescription outpatient drugs of any manufacturer which has entered into and complies with an agreement under Section 1927(a) of the Social Security Act will be a covered benefit for all Medicaid eligible TennCare members when prescribed by an authorized licensed prescriber, unless coverage is excluded or otherwise restricted by TennCare in accordance with the following:

(a) As provided by Section 1927(d) of the Social Security Act, hereinafter referred to as the Act, the following drugs or classes of drugs or their medical uses are allowed to be excluded from coverage or otherwise restricted: agents when used for anorexia or weight control, agents when used to promote fertility, agents when used for cosmetic purposes or hair growth, agents when used for the symptomatic relief of coughs and colds, agents when used to promote smoking cessation, nonprescription or "over-the-counter" ("OTC") drugs, even when prescribed by a physician, covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests and monitoring services be purchased exclusively from the manufacturer or its designee, and drugs described in Section 107(c)(3) of the Drug Amendments of 1962 and identical, similar, or related drugs (DESI, IRS and LTE) as described in Section 1903(i)(5) of the Social Security Act. TennCare will exclude from coverage all of the allowable exclusions described above, with the exception of OTC drugs prescribed as medically necessary for individuals under the age of 21, and pre-natal vitamins prescribed for pregnant women.

(b) Services or treatment received from Methadone treatment clinics will be excluded from coverage.

(c) Coverage of prescription drugs for adult beneficiaries 21 years of age or older, who are not receiving services in a nursing facility (or other facility for institutional care) or enrolled in a Home and Community Based Services (HCBS) waiver, will be limited to four prescriptions per

month. This coverage limitation shall not apply to medications or supplies included on the list attached to this State Plan as Attachment I, or to such other medications as may subsequently be designated by the State through appropriate policy issuances, and of which pharmacies, providers and beneficiaries shall be made aware through appropriate notice.

(2) No payment will be made for an innovator multiple source drug (brand name drug) if, under applicable State law, a less expensive multiple source drug could have been dispensed, but only to the extent that such amount exceeds the upper payment limit for such multiple source drug. In the event a prescriber indicates on the face of the prescription ("dispense as written") that he/she is requiring a specific brand name drug be dispensed for a specific TennCare member or if a TennCare member appeals coverage of a generic drug and the appeals process results in approval of a specific brand name drug, then the reimbursement methodology for that prescription will the same as that for innovator single source drugs covered under the TennCare pharmacy program.

(3) A prior approval system for drugs requiring prior authorization will comply with Section 1927 of the Act and be administered by the pharmacy benefits manager (PBM) or pharmacy benefits administrator (PBA) under contract to TennCare to provide those services. The prior authorization process provides for a turn-around response by either telephone or other telecommunications device within twenty-four hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a seventy-two hour supply of medication.

(4) Participating pharmaceutical manufacturers will be furnished drug rebate utilization data and allowed to audit this data as set forth and according to the Centers for Medicare and Medicaid Services (CMS) guidelines pursuant to the Act.

(5) As provided by the Act, a new drug manufactured by a company which has entered into a rebate agreement may be covered subject to prior approval, unless the drug is subject to the allowable exclusion categories provided by the Act.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT, DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

(6) As specified in section 1927(b)(3)(D) of the Act, notwithstanding any other provision of law, information disclosed by manufacturers shall not be disclosed by the State in a form which discloses the identity of a specific manufacturer or prices charged for drugs by such manufacturers, except as the Secretary determines to be necessary and/or to permit the Comptroller General to review the information provided.

(7) Separate agreements between the State and the manufacturers require CMS authorization. The State has CMS authorization for the collection of supplemental rebates that are negotiated with pharmaceutical manufacturers pursuant to the TennCare preferred drug list (PDL) as required by the Act. TennCare will report supplemental rebates from separate agreements to CMS.

(8) The state is in compliance with Section 1927 of the Social Security Act, except insofar as the State may have obtained a waiver of § 1902(a)(54) of the Social Security Act under § 1115 to authorize noncompliance with certain provisions of § 1927 for specific purposes related to carrying out a federally approved demonstration project. Except as otherwise specifically provided in this State Plan, the state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and applicable restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.

A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on August 13, 2003 and entitled, "State of Tennessee Supplemental Rebate Agreement," has been authorized by CMS.

Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

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All drugs covered by the program, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

(9) Adult beneficiaries 21 years of age or older shall be liable for nominal cost sharing in the expense of outpatient pharmacy services afforded to them under the State Plan, and shall be obligated to make nominal co-payments when receiving covered prescription drugs from a pharmacy or other provider, with the exception of generic drugs included on the State's preferred drug list and drugs in categories that have not been reviewed for the inclusion in the preferred drug list. Pharmacies or providers shall collect all applicable TennCare-required copays from TennCare members. Failure to make an applicable co-payment will not be a basis for delay or denial of any of the services described in Section 1916(a)(2) of the Social Security Act or implementing regulations at 42 C.F.R. 447.53(b). Services cannot be denied to any eligible recipient because of the individual's inability to pay the co-payment. This requirement does not apply to an individual who is able to pay. An individual's inability to pay does not eliminate his or her liability for the co-payment charges. A recipient is deemed unable to pay the co-payment if the recipient states to the pharmacist that he or she cannot pay. The amount of such co-payment will be $1.00 for each prescription filled of a branded drug on the State's preferred drug list, and $3.00 for non-preferred medications. Certain enrollees will be exempt from copay obligations, in accordance with 42 CFR 447.53(b).

(10) In accordance with the provisions of the Act, TennCare began the development and implementation of a preferred drug list (PDL) on July 1, 2003. TennCare will move to a single, statewide preferred drug list (PDL) for the entire pharmacy program. Furthermore, TennCare will employ a single pharmacy benefits manager (PBM) to process all TennCare pharmacy claims and respond to all prior approval requests.

Pursuant to 42 U.S.C. Section 1396r-8 the state is establishing a preferred drug list with prior authorization for drugs not included on the preferred drug list. Prior authorization will be provided with a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in emergency situations.

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Prior authorization will be established for certain drug classes, particular drugs or medically accepted indication for uses and doses.

The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.

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(11) Except as otherwise specifically provided in this State Plan, when a provider with prescribing authority prescribes a covered medication for a TennCare member, and the prescription is presented at a pharmacy that participates in the TennCare program, the member is entitled to either:

(a) The drug as prescribed, if the drug is covered by TennCare and does not require prior authorization; or

(b) The drug as prescribed, if the prescribing provider has obtained prior authorization; or

(c) An alternative medication, if the pharmacist consults the prescribing provider when the member presents the prescription to be filled, and the provider prescribes the substituted drug; or

(d) An emergency supply of the prescribed drug, if the pharmacist is unable, when the member presents the prescription to be filled, to obtain authorization from either TennCare or the designated TennCare point-of-sale (POS) pharmacy claims processor to fill the prescription as written or the prescribing provider's authorization to substitute an alternative medication. If the member does not receive the medication of the type and amount prescribed, the pharmacist shall immediately provide written notice of the right to appeal, including the right to request continuation of services pending appeal, as required by the *Grier* Revised Consent Decree. The member's entitlement to receive an emergency supply of the prescribed drug is subject to the provisions as set out below.

(12) The member is entitled to an emergency supply of the prescribed drug provided that:

(a) The manufacturer has a rebate agreement and the medication is not classified by the FDA or regarded by CMS to be less than effective (DESI, LTE or IRS drug); or

(b) The medication is not a drug in a non-covered TennCare therapeutic category or class of drugs or products such as: agents used for anorexia, weight loss or weight gain, agents used to promote fertility, agents not listed on the TennCare preferred drug list used for the symptomatic relief of cough and colds, agents used for cosmetic purposes or hair growth, agents used to promote smoking cessation, agents not listed on the TennCare drug preferred drug list which are prescription vitamins and mineral products, agents not listed on the TennCare preferred drug list which are nonprescription (over-the-counter) products and drugs. TennCare will exclude from coverage all of the allowable exclusions described above; or

(c) Use of the medication has not been determined to be medically contraindicated because of the member's medical condition or possible adverse drug interaction; or

(d) The prescriber did not prescribe a total quantity less than an emergency supply, in which case the pharmacist must provide a supply up to the amount prescribed.

(13) There are some cases in which it is not feasible for the pharmacist to dispense an emergency supply because the drug is packaged by the manufacturer to be sold as the original unit or because the usual and customary pharmacy practice would be to dispense the drug in the original packaging (inhalers, eye drops, topicals, etc.). When coverage of an emergency supply of a prescription would otherwise be required and when, as described above, it is not feasible for the pharmacist to dispense an emergency supply, it shall be the responsibility of TennCare to provide coverage for either the emergency supply or the usual dispensing amount, whichever is greater.

(14) Pharmacies should bill prescriptions for TennCare members with other third party insurance to the appropriate third party payer (primary insurer) and bill any applicable copays for covered drugs to TennCare.

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(15) Covered drugs under the TennCare Pharmacy Program shall be limited to drugs that meet one or more of the following criteria and are not excluded by any of the following criteria:

(a) Those legend drugs covered under the Medicaid Drug Rebate Program as described in Section 1927 (k) of the Social Security Act and outlined in the TennCare Pharmacy Program Preferred drug list.

(b) Legend and non-legend drugs which are covered and prescribed by an authorized prescriber and which may not be dispensed over the counter without a prescription, except this limitation of coverage shall not apply in the case of a child under the age of 21 for whom an over-the-counter (OTC) drug has been prescribed as medically necessary by a licensed medical professional, or to coverage of pre-natal vitamins when prescribed for a pregnant woman.

(c) Those drugs which are not included in the list of excluded therapeutic categories or classes contained in Section 1927(d) of the Social Security Act and listed above in (12)(a)(1), except to the extent such drugs may be expressly excepted from non-coverage or designated as covered under certain circumstances or for certain categories of beneficiaries under any provision of this State Plan.

(d) Those drugs not considered to be DESI, less-than-effective (LTE) or identical, related or similar (IRS) to DESI drugs.

(e) Drugs that are included on the State's formulary, except, where applicable, in a case where prior authorization is obtained for coverage of any such drug.

(f) Drugs that are not designated as excluded from coverage under Section 12.a.(1) or any other provision of this State Plan.

(g) Drugs that are not prescribed under circumstances, or for individuals, for which their use is designated as non-covered under Section 12.a.(1) or any other provision of this State Plan.

Attachment I
Pharmacy Shortlist

Medications that will continue to be available to patients **in an outpatient setting** (if provided by a participating health care provider) even after the physician office visit or outpatient facility visit limit has been reached **or** that will **not** count toward the 4 prescription limit when obtained through a participating retail pharmacy:

Specified drugs for the treatment of renal disease (iron preparations and dialysis medications)
TPN
Antineoplastic agents
Clotting factors
Antiviral agents specific to HIV treatment
Drugs specific to the treatment of Hep C
Drugs specific to the treatment of tuberculosis
Flu vaccine for high risk individuals
Prenatal vitamins

This list has been developed in consultation with state professional associations, attempting to take into account the following factors:

(1) actual budget constraints;
(2) associated severity of illness;
(3) likelihood that the patient will require multiple drugs; and
(4) abuse potential and current utilization levels.

Equipment and Supplies that will not count toward any limit and that will continue to be covered **in an outpatient setting** even after other benefit limits have been hit:

Home infusion supplies
Diabetic supplies
Asthma supplies

Important Note:

The Shortlist is a living document. As new medications become available that fall into the same or similar categories to those already on the list, they will be considered for inclusion on the list. In addition, the list will be reviewed in the regularly in the context of budget constraints and operational compliance and could be expanded or reduced based on the results of such review. State health associations will be involved in decision-making.

	HIC3 Description		Examples of Paid Claims	HIC3 Coding	HICL coding
Clotting Factors	Antihemophilic Factors	Factor VIIa	Novoseven	**M0E**	011639
		Factor VII	Advate	**M0E**	011418
			Recombinate	**M0E**	011418
			Kogenate FS	**M0E**	011418
			Helixate FS	**M0E**	011418
			Refacto	**M0E**	011418
		Anti-inhibitor Coagulant Complex	Autoplex T	**M0E**	**002740**
			Fieba VH Immuno	**M0E**	**002740**
		Antihemophilic factor/von Willebrand factor	Humate-P	**M0E**	017395
		Antihemophilic factor	Alphanate	**M0E**	011417
			Hemofil-M	**M0E**	011417
	Factor IX Preparations	Factor IX	Benefix	**M0F**	012793
			Bebulin VH	**M0F**	002741
			Mononine	**M0F**	021313
			Alphanine SD	**M0F**	021313
Iron Preparations	Hematinic, other	Epoetin	Procrit	**N1B**	004553
			Epogen	**N1B**	004553
		Darbepoetin	Aranesp	**N1B**	048578
	Iron replacement	Iron Dextran	Infed	C3B	**000733**
			DexFerrum	C3B	**000733**
		Sodium Ferric Gluconate Complex	Ferrlecit	C3B	**019948**
		Iron Sucrose	Venofer	C3B	**021773**
Dialysis Medications	Electolyte Depleters		Calcium Acetate	**C1A**	004884
			Sevelamar (Renagel)	**C1A**	018832
			SPS (Kayexalate)	**C1A**	013209
	Vitamin B preps		FA/Vit B Complex with C (Nephrocap)	C6B	**001061**
Anti-Virals	Antivirals, HIV Specific, Protease Inhibitor	Protease Inhibitors	Invirase	**W5C**	024470
			Fortovase	**W5C**	016624
			Norvir	**W5C**	010412
			Crixivan	**W5C**	010683
			Viracept	**W5C**	030366
			Lexiva	**W5C**	025662
			Agenerase	**W5C**	021177
			Agenerase	**W5C**	019079
			Reyataz	**W5C**	025390
	Antivirals, HIV specific, Protease Inhibitor Combo	Protease Inhibitor Combos	Kaletra	**W5M**	021582
	Antivirals, HIV specific, nucleotide analog RTI	Nucleotide Analog Reverse Trans Inhibitor	Viread	**W5I**	022937

	Antivirals, HIV specific nucleoside analog RTI	Nucleoside Rev Transcript Inhibitor	Videx	**W5J**	011013, 006508, 006510, 006221
			Epivir	**W5J**	024417
			Zerit	**W5J**	009060
			Hivid	**W5J**	006408
			Retrovir	**W5J**	004185
			Ziagen	**W5J**	018857
			Emtriva	**W5J**	025426
	Antivirals HIV specific nucleoside analog RTI combo	Nucleoside analog Reverse Trans Inhibitor	Combivir	**W5L**	014014
			Trizivir	**W5L**	021800, 022982
			Epzicom	**W5L**	026524
	Antiviral HIV specific nucleoside/nucleotide combo	Nucleoside/nucleotide combo	Truvada	**W5O**	026515
	Antivirals HIV specific non-nucleoside RTI	Non-nucleoside reverse trans inhibitor	Viramune	**W5K**	011592
			Rescriptor	**W5K**	012954
			Sustiva	**W5K**	018748
	Antivirals HIV specific fuseon inhibitor	Fuseon inhibitors	Fuzeon	**W5N**	025044
	Antivirals assoc with HIV	General antivirals	Foscavir	**W5A**	013221
			Cytovene (PO + IV)	**W5A**	009644
			Valcyte	**W5A**	022033
			Vistide	**W5A**	011506
	Eye antivirals	Eye antivirals	Vitravene	Q6V	**018834**
			Vitrasert	Q6V	**009644**
Flu Vaccine	Influenza virus vaccines		Influenza tri/split	**W7C**	
Hepatitis C	Hepatitis C treatment agents		Peg-interferon alfa-2a (Pegasys)	**W5G**	024035
			Peg-interferon alfa-2b	**W5G**	021367
			Ribavirin (Rebetrol)	**W5G**	004184
			Interferon alfa-2b and ribivirin (Rebetron)	**W5G**	018438
			Interferon alfacon-1 (Infergen)	**W5G**	015707

			Interferon alfa-2a (Roferon-A)	Z2G	**004527**
			Interferon alfa-2b (Intron A)	Z2G	**004528**
Anti-tubercular Agents	Anti-mycobacterium		Isoniazid	**W2E**	004080
			Rifabutin	**W2E**	007626
			Pyrazinamide	**W2E**	004084
			Ethambutol	**W2E**	004085
			Ethionamide	**W2E**	004086
			Aminosalicylic acid	**W2E**	004081, 004082, 004083
	Antitubercular antibiotics		Rifamate	**W1G**	004039
			Rifater	**W1G**	006296
			Rifampin	**W1G**	**004040**
			Cycloserine	**W1G**	004038
			Capreomycin	**W1G**	004037
			Rifapentine	**W1G**	018831
	Aminoglycoside		Streptomycin	W1F	004027
Antineoplastics	Alkylating agents	Nitrogen mustards	Chlorambucil	**V1A**	003894
			Cyclophosphamide	**V1A**	003893
			Ifosfamide	**V1A**	004570, 003903
			Mechlorethamine	**V1A**	004570, 003892
			Melphalan	**V1A**	007845, 003895
		Nitrosureas	Carmustine	**V1A**	003901
			Lomustine	**V1A**	003900
		Alkyl Sulfonates	Busulfan	**V1A**	003899
		Ethylenimines/Methylmelamines	Altretamine	**V1A**	006041
			Thiotepa	**V1A**	003898
		Platinum Coordination Complex	Carboplatin	**V1A**	003905
			Cisplatin	**V1A**	003902
			Oxaliplatin	**V1A**	016687
		Substituted Ureas	Hydroxyurea	**V1A**	003897
		Imidazotetrazine Derivatives	Temozolomide	**V1A**	020355

	Steroid antineoplastics	Estrogen/Nitrogen Mustard	Estramustine phos sod	**V1E**	003924
		Androgens	Testolactone	**V1E**	003922
	Antibiotic anti-neoplastics	Antibiotic anti-neoplastics	Streptozocin	**V1D**	003920
			Bleomycin	**V1D**	003918
			Dactinomycin	**V1D**	003914
			Mitomycin	**V1D**	003917
		Antibiotics, anthracyclines	Daunorubicin HCL	**V1D**	003919
			Daunorubicin liposomal	**V1D**	010804
			Doxorubicin	**V1D**	003916
			Doxorubicin, liposomal	**V1D**	010222
			Epirubicin	**V1D**	006578
			Idarubicin	**V1D**	006024
	Antineoplastics, Misc	Triazenes	Dacarbazine	**V1F**	003927
		Taxoids	Paclitaxel	**V1F**	010166, 007625
			Docetaxel	**V1F**	010280
		Podophyllotoxin Derivatives	Etoposide	**V1F**	011549, 003930
			Teniposide	**V1F**	004811
		Aromatase Inhibitors	Anastrozole	**V1F**	010249
			Letrozole	**V1F**	012351
			Exemestane	**V1F**	020803
		Enzymes	Asparaginase	**V1F**	003929
			Pegaspargase	**V1F**	008904
		Anthracenedione	Mitoxantrone	**V1F**	003932
		Methylhydrazine Derivatives	Procarbazine	**V1F**	003928
		DNA Topoisomerase Inhibitors	Irinotecan	**V1F**	010778
			Topotecan	**V1F**	011381
		Biological Response Modifiers	Aldesleukin	Z2G	**006402**
			BGC, Intravesical	**V1F**	004219
			Denileukin Diftitox	**V1F**	019075
			Levamisole	Z2G	**005811**
		Retinoids, antineoplastics	Tretinoin (Vesanoid only)	**V1F**	002468
		Rexinoids	Bexarotene	**V1N**	**020832**
				Q5N	**020832**
			Alitretinoin	Q5N	**019074**
		Misc	Mitotane	**V1F**	003925
			Porfimer	**V1R**	011790
			Talc Powder, sterile	**V1S**	002321
			Abarelix	**V1V**	025850
			Arsenic trioxide	**V1F**	021734

	Antimetabolites	Folic Acid Antagonists	Methotrexate	**V1B**	003905, 003906, 024819
			Pemetrexed	**V1B**	025905
		Pyrimidine analogs	Capecitabine	**V1B**	018385
			Gemcitabine	**V1B**	010798
			Cytarabine	**V1B**	003910
			Cytarabine, liposomal	**V1B**	020270
			Fluorouracil	**V1B**	003907
			Floxuridine	**V1B**	003909
		Purine analogs and related agents	Cladribine	**V1B**	007840
			Fludarabine	**V1B**	006308
			Mercaptopurine	**V1B**	003908
			Pentostatin	**V1B**	006304
			Thioguanine	**V1B**	003911
		DNA demethylation agents	Azacitidine	**V1B**	026361
	Antimitotic agents	Vinca alkaloids	Vinblastine	**V1C**	003912
			Vincristine	**V1C**	003913
			Vinorelbine	**V1C**	009614
	Hormones	Antiandrogens	Bicalutamide	**V1J**	010143
			Flutamide	**V1J**	003933
			Nilutamide	**V1J**	007876
		Antiestrogen	Tamoxifen	**V1T**	003926
			Toremifene	**V1T**	011632
			Fulvestrant	**V1T**	023523
		Gonadotropin-releasing hormone analog	Leuprolide	**V1O**	021994, 021102
			Goserelin	**V1O**	021114
			Triptorelin	**V1O**	023164
	Radiopharmaceuticals	Radiopharmaceuticals	Strontium-89	**V1G**	008779
			Samarium SM 153	**V1G**	013440
	Cytoprotective agents	Chemotherapy rescue/antidote agent	Amifostine	**V1I**	010704, 013015
			Dexrazoxane	**V1I**	009997
			Mesna	**V1I**	003934
			Leucovorin	**V1I**	001063
	Monoclonal antibodies	Antineoplastics antibody/antibody drug complex	Rituximab	**V1K**	016848
			Ibritumomab	**V1K**	023335, 023334
			Trastuzumab	**V1K**	018801
			Gemtuzumab	**V1K**	021218
			Alemtuzumab	**V1K**	022112
			Tositumomab	**V1K**	025481
			Zevalin	**V1K**	024430, 024431

				V1U	025481
		Antineoplastic egf receptor blocker rcmb mc antibody	Cetuximab	**V1W**	025947
		Antineoplastic hum vegf inhibitor recomb mc antibody	Bevacizumab	**V1X**	025963
	Protein tyrosine kinase inhibitors	Antineoplastic systemic enzyme inhibitor	Imatinib	**V1Q**	022096
	Epidermal growth factor receptor inhibitors	Antineoplastic systemic enzyme inhibitor	Cefitinib	**V1Q**	025178
	Proteasome Inhibitors	Proteasome Inhibitors	Bortezomib	**V1Q**	025202
		HER1/EGFR tyrosine kinase inhibitors	Erlotinib	**V1Q**	26745
					V1Q
Glucose regulating and monitoring agents	Test strips	HICL=006373, GSN=19756, 6373			
	Lancets	HICL=004422, 025583			
	Alcohol pads	HICL=004266			
	Glucose control solution	HICL=023579, GSN=19415			
	Meters	HICL=002748, 023088, 007894, 024300, 024299. gsn=6372			
	Syringes	HICL=004327, 023038, 023041, 023039, 023037, 023042, 023043, 024313, 024314, 024100, 023040, 024315, 025117, 025118			
Prenatal vitamins	Prenatal Vitamin preparations		Prenate, Zenate, etc	C6F	
Asthma Spacers				Y7A	**009021**
Large Volume Parenterals					
Coded by large volume fluid for quantities > 500ml, any additive will be covered					
Sodium Chloride	HICL 008254, 008643, GSN				

	1210, 1209				
Dextrose	HIC3 of C5K, C5L, C5M, HICL 000915, 000929				
Lactated Ringers	HIC3 of C1W				
Sterile Water	GSN 1166				
TPN					
Coded by Amino Acid, all additives will be covered					
Amino Acids	HIC3 of C5B				
Heplock					
Heplock of 10u/ml or 100u/ml	GSN 6551, 6552, 6531, 6532, 6541, 6542, 18063				
Saline Flush					
Coded up to 30cc vials	GSN 1218, 1221, HICL 003794				

STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE
729 CHURCH STREET
NASHVILLE, TENNESSEE 37247-6501

[Date to come]

Renard L. Murray
Associate Regional Administrator
Division of Medicaid
Centers for Medicare and Medicaid Services (CMS)
Atlanta Federal Center
61 Forsyth Street, S.W., Suite 4T20
Atlanta, GA 30303-8909

Dear Mr. Murray:

Action Transmittal 2005-7 is an amendment to the Tennessee Title XIX Medicaid State Plan, which is being forwarded to your office for review and approval. This plan amendment is being submitted to eliminate two drug classes. A copy of the public notice conducted in accordance with 42 CFR 447.205 is attached. ***[This document will be attached when the SPA is submitted to CMS.]*** We would appreciate the opportunity to work with you to coordinate the final effective date with the date of approval of our waiver amendment.

Should you have any questions or need additional information, please contact Susie Baird at (615) 741-0213.

Sincerely,

J. D. Hickey
Deputy Commissioner

JDH/D1085013

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 2005-7

2. STATE: TENNESSEE

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN X AMENDMENT TO BE CONSIDERED AS NEW PLAN ☐ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
42 CFR 440 and 441

7. FEDERAL BUDGET IMPACT:
a. FFY 2004/2005 $
b. FFY 2005/2006 $

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 3.1.A.1, Item 12, 12.a. (1)(d)
Attachment 3.1.B.1, Item 12, 12.a. (1)(d)

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:

10. SUBJECT OF AMENDMENT: Limitation on Amount, Duration and Scope of Medical Care and Services Provided – Prescribed Drugs.

11. GOVERNOR'S REVIEW *(Check One)*:
X GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME: J. D. Hickey

14. TITLE: Deputy Commissioner

15. DATE SUBMITTED:

16. RETURN TO:
Tennessee Department of Finance and Administration
Bureau of TennCare
729 Church Street
Nashville, Tennessee 37247-6501

Attention: George Woods

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

18. DATE APPROVED:

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:

22. TITLE:

23. REMARKS:

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE TENNESSEE

LIMITATION ON AMOUNT, DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

12.a. Prescribed drugs

(1)(d) TennCare will exclude from coverage all antihistamines and pharmaceutical products for the reduction of gastric acid, including H2 blockers and proton pump inhibitors, except when prescribed as medically necessary for individuals under the age of 21. There will be no exceptions to this coverage exclusion for adult beneficiaries.

D1095025

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE TENNESSEE

LIMITATION ON AMOUNT, DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

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D1105025

STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE
729 CHURCH STREET
NASHVILLE, TENNESSEE 37247-6501

[Date to come]

Mr. Renard Murray
Associate Regional Administrator
Division of Medicaid
Centers for Medicare & Medicaid Services (CMS)
Atlanta Federal Center
61 Forsyth Street, S.W., Suite 4T20
Atlanta, Georgia 30303-8909

Dear Mr. Murray:

Action Transmittal 2005-8 is an amendment to the Tennessee Title XIX State Plan which is being forwarded to your office for review and approval. The State of Tennessee has competitively secured the services of First Health Services Corporation to implement a preferred drug list/supplemental rebate program. This procurement was done through a competitive Request for Proposal process following state and federal guidelines for the procurement of services for Title XIX programs.

This State Plan Amendment is to allow for the collection of supplemental rebates from pharmaceutical manufacturers for the Medicaid program through the Michigan Multi-State Pooling Agreement (MMSPA) approved by CMS on April 22, 2004. The use of a preferred drug list and prior authorization program will increase the efficiency and economy of Medicaid operations and benefit the Medicaid population by holding down the rising cost of prescription coverage to the Medicaid program.

Through the procurement of the pharmacy benefit services, Tennessee has a choice of either developing state specific supplemental rebate contracts with pharmaceutical manufacturers, or becoming a participant in the MMSPA, that has been developed to allow States to pool their collective purchasing power to gain deeper discounts on prescription drugs for Medicaid beneficiaries. Through this State Plan Amendment, Tennessee is electing to join the MMSPA.

The States that are currently participants in the MMSPA are Michigan, Vermont, New Hampshire, Nevada, Alaska, Montana, Minnesota, and Hawaii. Tennessee is seeking CMS approval to join these states in the MMSPA through the CMS approved process of adding States to the pool. Attached to Tennessee's State Plan Amendment is a copy of the "New Participating State Amendment to Supplemental Drug-Rebate Agreement between the States of Michigan, Vermont, New Hampshire, Alaska and Nevada: First Health Services Corporation and the Manufacturer". This document is the CMS approved template that will be used with each manufacturer to add Tennessee to the MMSPA.

Tennessee is also including Exhibit A1 indicating that Tennessee does not have any non-Medicaid programs approved by CMS in the Medicaid State Plan.

Following is the Supplemental Rebate Agreement Questions followed by appropriate TennCare response:

1. Does the state receive a supplemental rebate or any revenue back from manufacturers in addition to the national Medicaid rebate? If so, does the state reduce the Medicaid expenditures under the state plan by the amount of the rebates or revenue?

   TennCare response:
   Yes, the State receives additional supplemental rebate. The Medicaid expenditures under the State Plan are reduced by the amount of the rebate.

2. Does the state receive any goods, services or other benefits for their Medicaid covered population from the pharmaceutical manufacturer? Does the manufacturer provide these goods, services or other benefits for including the manufacturer's drugs on a Medicaid preferred drug list? Does the state receive goods or services from a manufacturer if the manufacturer's drugs are not subject to prior authorization?

   TennCare response: No.

3. If the state receives goods or services from the manufacturer, what kinds of goods or services are provided? What is the value of these goods and services?

   TennCare's response: Not applicable

4. Does the state share the savings realized by these manufacturer goods, services, revenues and rebates with the federal government by offsetting total computable Medicaid expenditures by the costs of these services?

   TennCare's response: Not applicable

A copy of the public notice conducted in accordance with 42 CFR 447.205 is attached. ***[This document will be attached when the SPA is submitted to CMS.]*** We would appreciate the opportunity to work with you to coordinate the final effective date with the date of approval of our waiver amendment.

I look forward to gaining approval from CMS for this State Plan Amendment, if additional information is needed or if you have any questions, please contact me at (615) 741-0213.

Sincerely,

J. D. Hickey
Deputy Commissioner

JDH/D1025026

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL **FOR: HEALTH CARE FINANCING ADMINISTRATION**	1. TRANSMITTAL NUMBER: 2005-8	2. STATE TENNESSEE
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE	

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN X AMENDMENT TO BE CONSIDERED AS NEW PLAN ☐ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR 440 and 441	7. FEDERAL BUDGET IMPACT: a. FFY 2004/2005 $ b. FFY 2005/2006 $
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1.A.1, Item 12, 12.a. (8) Attachment 3.1.B.1, Item 12, 12.a. (8)	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: Attachment 3.1.A.1, Item 12, 12.a. (8) Attachment 3.1.B.1, Item 12, 12.a. (8)

10. SUBJECT OF AMENDMENT: Limitation on Amount, Duration and Scope of Medical Care and Services Provided – Prescribed Drugs.

11. GOVERNOR'S REVIEW *(Check One)*:

X GOVERNOR'S OFFICE REPORTED NO COMMENT

☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED

☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

☐ OTHER, AS SPECIFIED:

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13. TYPED NAME: J. D. Hickey	
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15. DATE SUBMITTED:	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:	18. DATE APPROVED:
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL:	20. SIGNATURE OF REGIONAL OFFICIAL:
21. TYPED NAME:	22. TITLE:

23. REMARKS:

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE TENNESSEE
LIMITATION ON AMOUNT DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

12.a. Prescribed drugs

(8) The state is in compliance with Section 1927 of the Social Security Act, except insofar as the State may have obtained a waiver of § 1902(a)(54) of the Social Security Act under § 1115 to authorize noncompliance with certain provisions of § 1927 for specific purposes related to carrying out a federally approved demonstration project. Except as otherwise specifically provided in this State Plan, the state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and applicable restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.

CMS has authorized the state of Tennessee to enter into the Michigan multi-state pooling agreement. The Amendment to the Supplemental Drug Rebate Agreement was submitted to CMS on _____ and has been authorized by CMS.

Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

All drugs covered by the program, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE TENNESSEE
LIMITATION ON AMOUNT DURATION AND SCOPE OF MEDICAL
CARE AND SERVICES PROVIDED

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CMS has authorized the state of Tennessee to enter into the Michigan multi-state pooling agreement. The Amendment to the Supplemental Drug Rebate Agreement was submitted to CMS on _____ and has been authorized by CMS.

Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

All drugs covered by the program, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

New Participating State Amendment to Supplemental Drug-Rebate Agreement Between The States of Michigan, Vermont, New Hampshire, Alaska and Nevada; First Health Services Corporation And (Manufacturer Name ("Manufacturer"))

WHEREAS, the State of Michigan, First Health Services Corporation ("First Health"), and Manufacturer have entered into a Supplemental Drug-Rebate Agreement (the "Agreement"), effective as of April 1, 2004**;** and

WHEREAS, the participating States as named in Section 8 below have become parties to the Agreement as Participating States by previous amendment or addenda; and

WHEREAS, additional states have indicated their willingness to become a new Participating State, as defined in Section 3.14 of the Agreement, and thereby participate in the State Supplemental Rebates (as defined in Section 3.19 of the Agreement) available under the Agreement.

Deleted:

Now, therefore, in consideration of the mutual covenants, promises, and conditions contained herein and in the Agreement, the parties agree as follows:

1. The State of Tennessee is hereby added as a party to the Agreement as a new Participating State, as defined in Section 3.14 of the Agreement.

2. This Amendment shall become effective upon the date determined in accordance with Section 3.16 of the Agreement.

3. An executed copy of this Amendment shall be sent via certified mail, return receipt requested to Manufacturer's address of record as set forth in the Agreement within five (5) business days of its execution by the parties. Any notice to Participating State shall be sent to the names and address in section 9 of this Exhibit:

4. This Addendum adds a new Participating State to the Agreement and does not otherwise change or alter the Agreement. The new Participating State(s) understand(s) and agrees to be bound by the terms of the Agreement.

5. The undersigned State acknowledges that manufacturer rebate pricing information is confidential information under applicable Federal law and shall be exempt from public disclosure pursuant to State Code Section 71-5-197.

6. The undersigned State represents that it has not requested authorization from CMS to include any state pharmaceutical assistance program within the rebate provisions of the Agreement. The above representation shall not prohibit the undersigned State from requesting CMS authorization to include (other) pharmaceutical assistance programs within the Agreement at a later date. Upon receipt of CMS authorization, State shall given written notice to Manufacturer of the date Manufacturer's Supplemental Covered Product is effectively placed on the preferred drug list of the undersigned State's non-Medicaid programs approved by CMS in the Medicaid state plan(s) by completing the attached Exhibit A1.

7. The approximate enrollment in the undersigned State's Medicaid program at the time of execution of this Amendment is _____.

8. As of the effective date of this Amendment, the following are all of the Participating States under the Agreement:

Michigan _____	_____Alaska_____
_Vermont_____	_____Nevada_____
_New Hampshire____	_____Tennessee_____

9. The contact information for each of the Participating States listed above in section 8 and new states shall be as follows:

State of Michigan	Department of Community Health Medical Services Administration Attn: Dave McLaury 400 S. Pine Street Lansing, MI 48933
State of Vermont	Director of Pharmacy Office of Vermont Health Access 103 South Main Street Waterbury, VT 05671-1201
State of Nevada	Division of Health Care Financing and Policy Nevada Department of Human Resources Mark Willden, Director 1100 East Williams Street Carson City, Nevada 89701
State of New Hampshire	State of New Hampshire Department of Health and Human Services Commissioner John Stephen 129 Pleasant Street Concord, NH 03301

State of Alaska

Dwayne Peeples
Director of Health Care Services
State of Alaska Health & Social Services Department
Health Care Services Division
4501 Business Park Boulevard, Ste. 24
Anchorage, AK 99503

State of Tennessee

[*Name to come]*
Bureau of TennCare
Tennessee Department of Finance and Administration
729 Church Street
Nashville, TN 37247-6501

STATE OF Tennessee ,	FIRST HEALTH SERVICES CORP
DEPARTMENT OF Finance & Administration	
By: State	By: _____
Name: _____	Name_____
Title: _____	Title: _____
Date: _____	Date: _____

D1014120

EXHIBIT A1

Participating State's Non-Medicaid Programs Approved by CMS in the Medicaid State Plan(s)

Participating State: Tennessee

Non-Medicaid programs approved by CMS in the Medicaid State Plan(s)- Date of Approval

1. ____None_____ _____
2. _____ _____
3. _____ _____
4. _____ _____
5. _____ _____
6. _____ _____

D1024120

Amendment to the Supplemental Drug-Rebate Agreement
Between
The State of Michigan, First Health Services Corporation
And
[Insert Manufacturer Name]

WHEREAS, the State of Michigan, First Health Services Corporation ("First Health"), and (Manufacturer") have entered into a Supplemental Drug-Rebate Agreement Contract # **[Insert Contract Number]** (the "Agreement"), effective as of **[Insert date]**; and

WHEREAS, the States of Vermont, Nevada, Alaska, and New Hampshire have become parties to the **Michigan Multi-State Pooling Supplemental Rebate Agreement** by executing the Addendum provided for in Section 9.9 of the Agreement; and

WHEREAS, the states of Hawaii and Tennessee have evidenced an intent to become parties to the Agreement; and

WHEREAS, the Centers for Medicare and Medicaid Services ("CMS") is now requiring certain changes to the Agreement before it will authorize them; and

WHEREAS, additional states have indicated their willingness to become Participating States, as defined in Section 3.14 of the Agreement, and thereby participate in the State Supplemental Rebates (as defined in Section 3.19 of the Agreement) available under the Agreement.

NOW, THEREFORE, IN CONSIDERATION OF THE MUTUAL CONVENANTS, PROMISES AND CONDITIONS CONTAINED HEREIN, THE PARTIES AGREE TO THE FOLLOWING AMENDMENTS TO THE AGREEMENT.

1. Section 1.1: The states of Vermont, Nevada, Alaska, and New Hampshire are added on the second line and "State" is changed to "States."

2. Any and all references to "U.S. Territories" is stricken from the entire Agreement.

3. Section 2.1: On line 3 "State" is changed to "States" and the clauses beginning immediately thereafter with "and/or" are deleted down to "Participating States" on line 8. On the third line, the words "CMS approved state-funded programs" are replaced with "non-Medicaid programs approved by CMS in the Medicaid state plan(s)".

4. Section 3.3 is deleted in its entirety and "Client State(s)" is stricken from the entire agreement.

5. Section 3.11: "State" within the parentheses on line one is made "States." In line three, "HHS approved state-funded programs" is deleted and replaced with "non-Medicaid programs approved by CMS in the Medicaid state plan(s)."

6. Section 3.12: This section is deleted in its entirety. "First Health Client's States" and "FH Client's States" are stricken from this Agreement.

7. Section 3.14: This section is modified to read as follows:

"Participating State(s)" means the (i) States as named in Section 1.1 hereof, and (ii) other states that, subsequent to the execution of this Agreement by the States, elect to participate under this Agreement and have all necessary authorizations and approvals from CMS to do so. Unless otherwise approved by CMS on a state-by-state basis. Participating States shall be limited to ones that have a CMS approved contract under which First Health has been engaged to provide PBA Services to that state. For each new Participating State, a unilateral amendment ("New Participating State Amendment") to this Agreement shall be executed by the new Participating State and First Health and sent to the Manufacturer prior to the Participation Commencement Date. Each Participating State, including the new Participating State, must submit a state plan amendment adding the new Participating State to the Agreement to CMS for approval. A copy of the form Amendment is attached hereto as Exhibit A."

8. Section 3.16: This section is modified to read as follows:

"Participation Commencement Date" means the latter of the date (i) a Manufacturer's Supplemental Covered Product is effectively placed in a Participating States Preferred Drug List Program by distribution of it (via website or otherwise) to providers and prescribers, or (ii) the New Participating State Amendment is received by the Manufacturer from a new Participating State. It is the date when the Participating States entitlement to a rebate from the Manufacturer begins to accrue."

9. Section 3.20: On the second line: the phrase "state funded, HHS approved program" is deleted and replaced with "non-Medicaid programs approved by CMS in the state plan(s) as provided in Section 2.1 hereof".

10. Section 5.1: The last sentence of this section is modified to read:

"Each Participating State will notify Manufacturer and First Health, within ten (10) business days of adoption and publication of anew or revised Preferred Drug List, when Manufacturer's Supplemental Covered Product is added to the Participating State's Preferred Drug List by providing Manufacturer and First Health a copy of the Preferred Drug List in accordance with the notice provisions of Section 9.2 hereof."

11. Section 8.3 is modified by deleting items (ii) and (iii) so that it now reads as follows:

"Termination by a FH Client of its PBA Services Agreement with First Health shall, as of the same termination effective date, terminate this Agreement as to that Participating State."

12. Section 9.2: This section is modified by adding the notice addresses for Nevada, Vermont, New Hampshire, and Alaska, which are as follows:

Director of Pharmacy
Office of Vermont Health Access
103 South Main Street
Waterbury, VT 05671-1201

Division of Health Care Financing and Policy
Nevada Department of Human Resources
Mark Willden, Director
1100 East Williams Street
Carson City, Nevada 89701

State of New Hampshire Department of Health and Human Services
Commissioner John Stephen
120 Pleasant Street
Concord, NH 03301

Dwayne Peeples
Director of Health Care Services
State of Alaska Health & Social Services Department
Health Care Services Division
4501 Business Park Boulevard, Ste. 24
Anchorage, AK 99503

13. Section 9.9: This section is modified to read as follows:

"This Agreement will not be altered except by (1) an amendment in writing signed by all the parties, other than (ii) in the case of the addition of a new Participating State(s), by its execution of the New Participating State Amendment, both (i) and (ii) of which shall require the approval of CMS. It is acknowledged that the intent of the previous sentence is that the addition of new Participating State(s) by amendment shall only require the consent of First Health and the approval of CMS, not Manufacturer. Manufacturer agrees that any Participating State may be added to this Agreement by amendment and that said Participating State's covered Medicaid (and other non-Medicaid programs approved by CMS in the Medicaid state plan(s)) lives shall apply to the provision of Schedules 2 and 3 and will affect the rebates to all Participating States in accordance with Schedules 2 and 3. The New Participating State Amendment shall be executed by First Health and the new Participating State with a copy provided to Manufacturer for its records. Other than as stated herein, no individual is authorized to alter or vary the terms or make any representation or inducement relative to it, unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Participating State(s), First Health, and the Manufacturer."

14. Section 9.11: In the second line, replace "other state funded" with "non-Medicaid programs approved by CMS in the Medicaid state plan(s)".

15. Except as expressly amended herein, all other terms, conditions and provisions of the Agreement shall remain in full force and effect and the parties hereto hereby ratify and confirm the same as of the date hereof. To the extent that any provisions of this Amendment conflict with the provisions of the Agreement, the provisions of Amendment shall control.

As evidence of their agreement to the foregoing terms and conditions, the parties have signed below:

MANUFACTURER

By:_____ Date: _____
Name:_____
Title: _____

FIRST HEALTH SERVICES CORPORATION

By: _____ Date: _____
Name: Teresa R. DiMarco
Title: President

STATE OF MICHIGAN, DEPARTMENT OF COMMUNITY HEALTH

By:_____ Date: _____
Name:_____
Title: _____

STATE OF VERMONT, DEPT. OF PREVENTION, ASSISTANCE, TRANSITION AND ACCESS

By:_____ Date: _____
Name:_____
Title: _____

STATE OF NEVADA, DEPARTMENT OF HEALTH CARE FINANCING AND POLICY

By:_____ Date: _____
Name:_____
Title: _____

STATE OF ALASKA, DIVISION OF HEALTH CARE SERVICES

By:_____ Date: _____
Name:_____
Title: _____

STATE OF NEW HAMPSHIRE DEPARTMENT OF HEALTH & HUMAN SERVICES

By:_____ Date: _____
Name:_____
Title: _____